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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Richard J. BUCALA, et al. ART UNIT: 1644
SERIAL NO.: 09/557,823 EXAMINER: Patrick J. Nolan
FILING DATE: April 25, 2000
FOR: METHOD FOR DETERMINING MIF CONTENT

AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
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SIR:

Response to the outstanding Office Action dated August 12, 2004, entry of the following amendments is respectfully requested.

1-65 (Canceled).

66. (Currently Amended) A diagnostic method for determining the amount of macrophage migration inhibitory factor (MIF) protein in a sample, comprising:

(a) ~~obtaining a~~ contacting an anti-MIF antibody to the sample; and

(b) determining the amount of MIF protein in the sample using an immunoassay ~~with an anti-MIF antibody~~, wherein the immunoassay is selected from the group consisting of ELISA, radioimmuno assay (RIA), immunoprecipitation, immunohistocytochemistry, and Western analysis, and wherein said MIF protein is the human MIF protein having a molecular weight of approximately 12.5 kDa and having MIF biological activity, and wherein the anti-MIF antibody binds specifically to the MIF protein.

67. (Previously Presented) The diagnostic method of Claim 66, wherein the sample is selected from the group consisting of blood, serum, urine, lymph, saliva, tumor tissue, placental tissue, umbilical cord tissue, amniotic fluid, chorionic villi tissue and combinations thereof.

68. (Previously Presented) The diagnostic method of Claim 66, wherein the anti-MIF antibody is a monoclonal antibody or antigen-binding fragment or fusion protein thereof.

69-72 (Canceled).

73. (Previously Presented) The diagnostic method of Claim 66, wherein the sample is from a patient that is known or suspected to be suffering from a condition or disease caused by cytokine-mediated toxicity.

74. (Previously Presented) The diagnostic method of Claim 73, wherein said condition or disease caused by cytokine-mediated toxicity is selected from the group consisting of endotoxin-induced septic shock, endotoxin-induced toxic shock, shock, inflammatory diseases, graft versus host disease, autoimmune diseases, acute respiratory distress syndrome,

granulomatous diseases, chronic infections, transplant rejection, cachexia, asthma, viral infections, parasitic infections, malaria, and bacterial infections.

75. (Previously Presented) The diagnostic method of Claim 66, wherein the sample is a member selected from the group consisting of body fluid, tissue and cell lysate.

76-80 (Canceled).

81. (Currently Amended) A method for determining an amount of macrophage migration inhibitory factor (MIF) protein in a sample, comprising determining the presence or absence of the MIF protein in the sample using a direct or indirect detection technique and wherein the MIF protein is human MIF having a molecular weight of approximately 12.5 kDa, [[and]] containing the amino acid sequence of SEQ ID NO: 5, and having MIF biological activity.

82. (Previously Presented) The method of Claim 81, wherein the method comprises determining the amount of MIF present in the sample.

83. (Withdrawn) The method of Claim 81, wherein the determination of the presence or absence of MIF is accomplished directly by collecting data measurements of the intact sample.

84. (Withdrawn) The method of Claim 81, wherein the determination of the presence or absence of MIF is accomplished indirectly by collecting data produced after treating the sample to allow determination if MIF is present or absent.

85. (Currently Amended) A diagnostic method for determining an amount of macrophage migration inhibitory factor (MIF) protein in a sample, comprising:

(a) ~~obtaining a~~ contacting an anti-MIF antibody to the sample; and

(b) determining the amount of MIF protein in the sample using a direct or an indirect detection technique and wherein the MIF protein is human MIF, having a molecular weight of approximately 12.5 kDa, [[and]] containing the amino acid sequence of SEQ ID NO: 5 and having MIF biological activity.

86. (Withdrawn) The diagnostic method of Claim 85, wherein the direct detection technique is mass spectrometry or circular dichroism spectroscopy.

87. (Currently Amended) The diagnostic method of Claim 85, wherein the direct or indirect detection technique involves an immunoassay.

88. (Previously Presented) The diagnostic method of Claim 85, wherein the sample is selected from the group consisting of blood, serum, urine, lymph, saliva, tumor tissue, placental tissue, umbilical cord tissue, amniotic fluid, chorionic villi tissue and combinations thereof.

89. (Previously Presented) The diagnostic method of Claim 85, wherein the sample is a member selected from the group consisting of body fluid, tissue and cell lysate.